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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,657	09/29/2004	Teruyuki Yatabe	029650-158	2288
21839	7590	10/17/2006		
BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER HUH, BENJAMIN	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/509,657

Applicant(s)

YATABE ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 & 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Figge (US Patent No. 3448740). The Figge reference discloses an injection needle having a first ground facet with respect to element 15, 12", & 13", formed on a distal end of a needle tube and at least two ground facets 12 ' & 13' both seen as separate facets subsequently formed to provide a needle point 14, characterized in that a plane which crosses said first ground facet perpendicularly thereto and comprises a central axis of said needle tube is regarded as a central plane; and the needle point is not present on said central plane, as seen in figures 1-4.

With regards to claim 2, wherein the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said first ground facet in the direction of a minor axis thereof as seen in figures 1-4.

With regards to claim 6, wherein the injection needle of Figge would be fully capable of piercing a silicone rubber sheet having a thickness of 0.5 mm at a penetration speed of 10 mm/min. with an initial value of the load with respect to a

penetration distance being 6 gf/mm or less due to it's size, shape, and ability to work in the environment.

Claims 3 & 5 are rejected under 35 U.S.C. 102(b) as anticipated by Baldwin et al (US Patent No. 3071135). The Baldwin reference discloses an injection needle in figures 1-4 & 7 having an edge surface comprising three ground facets formed on a distal end of a needle tube to provide a needle point 14, characterized in that one of the ground facets which is remotest from said needle point is regarded as a first ground facet 17 which is deemed to be of a substantially elliptical shape possessing a major axis, and the other ground facets as a second ground facet 12 and a third ground facet 13, wherein the second ground facet and the third ground facet being formed on different sides of the major axis of the first ground facet, wherein the second ground facet is seen to be facet 12 on the left of the needlepoint and the third ground facet is seen to be facet 13 which is on the right side of the needlepoint or vice versa; and an angle α between said first ground facet and a central axis of said needle point, an angle ϕ between said second ground facet and the central axis of said needle point, and an angle θ between said third ground facet and the central axis of said needle point are related to each other by: $\alpha < \phi$, $\alpha < \theta$, and ϕ not equal to θ , see figures 1-4 & 7.

With regards to claim 5, wherein the length of said second ground facet in the direction of the central axis and the length of said third ground facet in the direction of the central axis are in the range from 20 to 80% of the whole length of the ground facets

in the direction of the central axis, as seen in figures 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 & 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figge (US Patent No. 3448740) in view of Baldwin et al (US Patent No. 3071135). Even though the Figge reference does not explicitly disclose multiple facets at different angles attention is directed to Baldwin. The Baldwin reference teaches the use of a multi-faceted needle in order to reduce pain perceived by the patient upon an injection due to the facets. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Figge with the facets of Baldwin in order to provide less coring and less pain perception to the patient.

With regards to claim 4, wherein a plane which crosses said first ground facet perpendicularly thereto and comprises the central axis of said needle tube is regarded as a central plane; and the minimum distance between said needle point and said central plane is in the range from 3 to 20% of the maximum outside diameter of said edge surface in the direction of a minor axis thereof, as would be seen in Figge figures 1-4.

With regards to claim 7, wherein the injection needle of Figge in view of Baldwin would be fully capable of piercing a silicone rubber sheet having a thickness of 0.5 mm at a penetration speed of 10 mm/min. with an initial value of the load with respect to a penetration distance being 6 gf/mm or less due to it's size, shape, and ability to work in the environment.

Response to Arguments

Applicant's arguments filed 7/27/06 have been fully considered but they are not persuasive.

Applicant argues that Figge does not disclose the first ground facet and that there is no plane which crosses the first ground facet perpendicularly thereto, the examiner disagrees. The definition of a facet can be seen to be "a small plane surface or a smooth surface", therefore the examiner sees the sections 15, 12", 13" to be the first ground facet. Now even though the claim states it to be a ground facet, the facet does not need to be ground since it would be product by process and wherein the instant claim is an apparatus claim. Therefore, the facet of Figge is still found to read on the claim of the ground facet and also wherein there is a plane which crosses the first ground facet perpendicularly thereto since it does not state at what point on the facet the plane is being used with respect to.

Applicant argues that Baldwin does not disclose an substantially elliptical shape possessing a major axis and that the second ground facet and the third ground facet are formed on different sides of the major axis of the first ground facet, the examiner

disagrees. Due to the changes due to the amendment the applicant is first directed to the rejection above with respect to claim 3, also wherein the first facet 17 is seen to be substantially elliptical since in the figures the facet is seen to be substantially elliptical due to it's size and shape. Last the second and third facets are seen to be on the different sides of the major axis since element 12 can be seen to be two different independent facets on the left and right side of the major axis and element 13 can be seen to be two different independent facets on the left and right side of the major axis, and therefore one of the facets that comprise element 12 can be seen to be left of the major axis and one of the facets that comprise element 13 can be seen to be right of the major axis or vice versa.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

